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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,077	06/23/2003	Stephen Suffin	10701-011	1225

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EXAMINER	
JONES, DAMERON	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,077	SUFFIN, STEPHEN	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-39 and 46-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the preliminary amendment filed 6/23/03 wherein the specification was amended. In addition, it is noted that Applicant requested that claims 1-39 and 46-49 be withdrawn from consideration.

Note: Claims 1-49 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a method of determining some type of effect on the central nervous system of a new or known drug as set forth in independent claim 40.

STATUTORY DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claim 40 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 49 of copending Application No. 10/193,735. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

112 FIRST PARAGRAPH REJECTIONS

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 40-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the effects of a drug on brain imbalances using quantitative EGG (electroencephalography), does not reasonably provide enablement for determining all effects of a new or known drug on the central nervous system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue

experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method of determining the effect of a new or known drug on the central nervous system as set forth in independent claim 40.

(2) State of the prior art

The references of record do not indicate all specific effects or class of effects in combination with various drugs that are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 40 encompasses a vast number of possible effects that may be analyzed and new and known drugs. Applicant's specification does not enable the public to make or use such a vast number of possible drugs in combination with all possible effects that may be determined from the central nervous system.

(4) Level of predictability in the art

The art pertaining to the various effects on the central nervous system in combination with new and known drugs is highly unpredictable. Determining the types of drugs or class of drugs in combination with the effect of interest requires various

experimental procedures and without guidance that is applicable to all effects that affect the central nervous system, there would be little predictability in performing the claimed invention. Hence, there is little predictability in performing the claimed invention, absent some guidance.

(5) Amount of direction and guidance provided by the inventor

Independent claim 40 encompasses a vast number of new and known drugs and effects of the central nervous system. Applicant's limited guidance does not enable the public to prepare such a numerous amount of new and known drugs in combination with determining its effect on the central nervous system. There is no directional guidance for the new or known drugs in combination with the effect on the nervous system. As a result, there is no enablement for all possible permutations and combinations of the new and known drugs and various effects on the central nervous system.

(6) Existence of working examples

Independent claim 40 encompasses a vast number of new and known drugs and effects of the central nervous system. Applicant's limited working examples do not enable the public to prepare such a numerous amount of drugs-central nervous system combinations. While Applicant's claims encompass a plethora of possible new and known drugs and effects they have on the central nervous system, the specification provides limited guidance and working examples.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible new and known drugs and effects known that may be determined from the central nervous system.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on all new and known drugs and their effects on the central nervous system. However, one of ordinary skill in the art would not be able to ascertain what is encompassed in the claims as written. Applicant

is respectfully requested to clarify the invention in order that one may determine what is being claimed.

103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slaweck et al (Peptides, 1999, Vol. 20, pages 211-218).

Slawecki et al disclose the neurophysiological effects of intracerebroventricular administration of urocortin, a corticotropin releasing factor related peptide. The effects of intracerebroventricular administration of three doses of urocortin on the electroencephalogram (EEG) and event-related potentials (ERPs) in rats were studied. Study results indicate that urocortin administration decreased the latency of the P3 component of the ERP in the amygdale and hippocampus. Also, the predominate effect of urocortin infusion of EEG spectral activity was an increase of power in the frontal cortex and a decrease in EEG stability in the frontal cortex and amygdale. Such neurophysiological effects, overlap some of those of corticotrophin releasing factor and are consistent with the behavioral profile described following urocortin administration in rats (see entire document, especially, abstract; pages 212-213, 'Methods'; pages 213-

214, 'Results; page 216, right column through page 217, right column). However, Slawecki et al fail to specifically state that pre-administration data was determined prior to analyzing the data after administering urocortin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to analyze the subject's pre-administration data because Slawecki et al disclose that initially, the rats weight was obtained (page 212, 'Subjects'); EEG and ERP recording were obtained during the surgical procedure and rats were allowed two weeks to recover before actual testing started (page 212, columns 1-2, bridging paragraph). In addition, a skilled practitioner in the art would recognize that Slawecki et al were obviously comparing data with that obtained in other studies since it stated that the results obtained from the behavioral profile of neurophysiological effects of urocortin are consistent with corticotropin releasing factor . Thus, both Slawecki et al disclose a method of deterring behavioral effects on a subject's nervous system comprising administering a drug to a subject, analyzing neurophysiologic information, and analyzing the subject's post drug administration. As set forth in independent claim 40.

SPECIFICATION

11. The disclosure is objected to because of the following informalities. The phrase 'and its continuation 09/930,632 filed on August 15, 2001, which, in turn, claim benefite..1997' is not consistent with the US Patent and Trademark Office record. In particular, the continuing data appearing on the file cover of the instant invention reads,

'This application is a DIV of 09/501,149 filed 2/9/2000, which is a CIP of 09/148,591 filed 9/4/1998, which claims benefit of 60/058,052 filed 9/6/1997'. Thus, Applicant is respectfully requested to make the appropriate corrections in order that the data appearing on the file cover and that disclose in the first line of the specification are consistent with one another.

Appropriate correction is required.

COMMENTS/NOTES

12. It should be noted that while Applicant is claims priority from 09/501,1149; 09/148,591; and 60/058,052, the instant invention is broader than the disclosure of those applications. Thus, a priority date back to 9/6/1997 for 60/058,052 does not apply for the entire scope of the claims. If Applicant is in disagreement with the Examiner's position, it is respectfully requested that page(s) and line number(s) be pointed out for support of independent claim 40 as written.

WITHDRAWN CLAIMS

13. Claims 1-39 and 46-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

Note: It is duly noted that Applicant has requested that the claims be withdrawn because they are being examined in another application. However, if it is Applicant's intent that the withdrawn claims be canceled, Applicant is respectfully requested to cancel the withdrawn subject matter.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

May 2, 2005